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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/376,430	08/18/99	MOORE	P PF466P1

HM22/0315

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EXAMINER	
O HARA,E	
ART UNIT	**PAPER NUMBER**
1646	8

DATE MAILED: 03/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1- File Copy

PTO-90C (Rev. 2/95)

Office Action Summary

Application No.	Applicant(s)
09/376,430	Moore et al.
Examiner	**Group Art Unit**
Eileen B. O'Hara	1646

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-23 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-23 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Claims 1-23 are pending in the instant application.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 14, 15 and 21, drawn to polynucleotides, vectors, host cells and a recombinant method of making a polypeptide, classified in class 536, subclass 23.5, class 435, subclasses 320.1, 252.3 and 69.1, for example.

II. Claims 11, 12 and 16, drawn to polypeptides, classified in class 530, subclass 350.

III. Claim 13, drawn to an antibody, classified in class 530, subclass 388.22.

IV. Claim 17, in so far as it is drawn to a method of treating a disease by administering a polypeptide, classified in class 514, subclass 2.

V. Claim 17, in so far as it is drawn to a method of treating a disease by administering a polynucleotide, classified in class 514, subclass 44.

VI. Claim 18, drawn to a method of diagnosing a pathological condition by determining the presence or absence of a mutation in a polynucleotide, classified in class 435, subclass 6, for example.

VII. Claims 19 and 20, drawn to methods of diagnosing a pathological condition by determining the presence or amount of polypeptide and identifying a binding partner to a polypeptide, both by binding assays, classified in class 435, subclass 7.1, for example.

VIII. Claim 22, drawn to a method of identifying an unspecified activity in a biological assay, class and subclass undeterminable.

IX. Claim 23, drawn to a product of unspecified constitution identified by a screening assay, class and subclass undeterminable.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of invention I encode the proteins of invention II. The polynucleotides have utility for the recombinant production of the protein in a host cell. Although the polynucleotides and proteins are related since the polynucleotides encode the specifically claimed proteins, they are distinct inventions because the protein products can be made by another materially different process, such as by synthesis or purification from the natural source. Further, the polynucleotides may be used for processes other than the production of the proteins, such as nucleic acid hybridization assays.

Invention I and each of inventions V, VI and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the polynucleotides can be used in the method of treatment by gene therapy of invention V, but they can also be used in a method of hybridization to detect mutations as in invention VI or in a method of assaying for a biological activity by expression of the nucleic acid in a cell, all of which are materially different methods.

The proteins of invention II are related to the antibodies of invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural receptor of the protein.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of invention II are used in a method of treatment by administering those polypeptides of invention IV, but they can also be used in a method of producing antibodies.

Inventions II and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different

functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the proteins of invention II are not used or defined in the method of assaying an unspecified activity by expressing polynucleotides.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides administered in invention V can encode the polypeptides, but the polypeptides may also be used in a method of making antibodies. Invention II and invention V are related in that the polynucleotides encode the polypeptides of invention II, and the method of gene therapy may control expression of the polypeptide.

Inventions II and VII are also related as product and process of use. In the instant case the polypeptides can be used in a method of identifying a compound that will bind to it, but it can also be used in a method of making antibodies.

Inventions II and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are proteins of different constitutions and have different structures and activities.

Inventions I and each of inventions III and IV are related as a process of making and a process of using a common product. The polynucleotides of invention I encode the polypeptide,

which is the cognate antigen necessary for production of the antibody of invention III and which is used in the method of treatment of invention IV, but the nucleotides may also be used as probes in a method of hybridization, which are materially different methods. The processes are patentably distinct because of different starting and ending points, method steps and goals.

Invention I and invention VII are related in that the polynucleotide encodes the polypeptide, which is measured in a method of diagnosing.

Invention I and invention IX are related in that the polynucleotides are used in a method of identifying a biological activity resulting from a unknown protein, and invention IX is the protein identified.

Invention II and invention VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptides are not used or required in the method of diagnosis by nucleic acid hybridization.

Invention III and invention VII are related in that the antibody of invention III can be used in a method of measuring the amount of polypeptide, but the antibody can also be used in a method of therapy.

Invention III and each of inventions IV-VI, VIII and IX are unrelated. The antibody of invention III is not used or defined in the methods.

Invention IX and each of inventions IV-VI, VIII and IX are unrelated. The protein of unspecified activity of invention III is not used or defined in the methods.

Inventions IV-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of the different inventions require different starting compounds and have different steps and goals.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the need for non-coextensive literature search, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D

Eileen B. O'Hara 3/10/00

Patent Examiner

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER